

finding that a causal relationship existed between the misrepresentation and the injury." ).

From a superiority point of view, it makes sense to try this case with the Medicare Part B beneficiaries' trial, and management issues are not insuperable because damages are formulaic: TPPs paying MediGap-type supplemental insurance paid some or all of the 20% copayment, which in turn was based on AWP. See Klay, 382 F.3d at 1259-60 ("Particularly where damages can be computed according to some formula, statistical analysis, or other easy or essentially mechanical methods, the fact that damages must be calculated on an individual basis is no impediment to class certification."). In addition, the trial of a statewide class will provide important information for an accurate evaluation of claims under other states' laws. Cf. Bridgestone/Firestone, 288 F.3d at 1020 ("Once a series of decisions or settlements has produced an accurate subset of the claims . . . the others in that subset can be settled or resolved at an established price." ).

**C. THIRD-PARTY PAYOR PHYSICIAN-ADMINISTERED CLASS  
(NON-MEDICARE PART B)**

Plaintiffs seek to include as part of the physician-administered class all TPPs that pay for physician-administered drugs outside the context of Medicare Part B and consumers that make percentage-based co-payments for these drugs under their private insurance plans. Defendants do not dispute that the

class meets the numerosity/commonality/typicality/adequacy requirements of Fed. R. Civ. P. 23(a), and I find that it does.<sup>24</sup> However, defendants do argue that individual factual and legal issues predominate over common ones because (1) each TPP had a different level of knowledge regarding the spread; and (2) each TPP negotiated separate agreements with doctors or groups of doctors. Plaintiffs argue that the key factual issue, the use of AWP, is common to the entire class because most drug reimbursements in physician-administered contracts are based on AWP. (Hartman Rebuttal ¶ 21(b).) Studies show that the percentage discount off of AWP in the physician-administered context mostly varies from 0 to 10%, with an average reimbursement of 98% of AWP. (Rosenthal 10.)

Plaintiffs rely heavily on their expert, Hartman, to show liability and aggregate damages based on the common use of AWP. In evaluating a motion for class certification, one of the thorniest issues is deciding the weight to be accorded an expert's opinion. "The question for the district court at the

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<sup>24</sup> The parties did not separately address whether a TPP can serve as a typical representative of its own plan beneficiaries in the context of non-Medicare Part B physician-administered drugs. Unlike in the Medicare Part B context, here the TPP serves as the intermediary for its plan beneficiaries in negotiating with providers over reimbursement rates, and no conflict is immediately apparent. Plaintiffs have not taken the position that these plan beneficiaries could prevail even if their plans do not. In the absence of a challenge, or better briefing, I do not dwell on the point.

class certification stage is whether plaintiffs' expert evidence is sufficient to demonstrate common questions of fact warranting certification of the proposed class, not whether the evidence will ultimately be persuasive." Visa Check, 280 F.3d at 135. "[T]he Court's inquiry is limited to whether or not the proposed methods [for computing damages] are so insubstantial as to amount to no method at all." Klay, 382 F.3d at 1259 (citation omitted) (alteration in original). Plaintiffs need not "have selected a particular econometric model for demonstrating impact (or proving damages) at the class certification stage." In re Linerboard Antitrust Litig., 305 F.3d 145, 155 (3d Cir. 2002). However, it is not permissible to use methods such as averaging damages to sweep individual issues under the judicial rug. Bell Atl. Corp. v. AT&T Corp., 339 F.3d 294, 304-05 (5th Cir. 2003) (finding that large number of independent factors that would affect what, if any, damages were suffered by each class member could not be approximated into an average damages amount).

Hartman believes that providers like doctors are natural targets of the AWP scheme because they have the power to move market share. (Hartman Decl. Exec. Summ.) Acknowledging that TPPs typically expect that AWP is larger than the average sales price ("ASP") by a "reasonably predictable amount" (Hartman Decl. ¶ 10), Hartman intends to calculate the spreads for the drugs allegedly subject to the AWP scheme and compare those spreads to

"but for" spreads, that is, spreads for comparable drugs that are unaffected by the AWP scheme and fraud.<sup>25</sup> As a cross-check, he will compare the calculated "but for" spread with industry-wide surveys. In addition, under the "revealed preferences" method, Hartman will calculate the expected spread by examining the contracts for the drugs affected by the alleged fraud to determine what the parties expected the spread between AWP and the ASP to be, and compare that expected spread with the actual spread. (Hartman Rebuttal ¶ 50 ("Simply stated, economic agents reveal their preferences, and implicitly the information they relied on, by their actual market decisions and behavior.").) Hartman estimates that the range of actual reimbursement rates in TPP contracts with providers in the self-administered context was AWP minus 13% to 17% (Hartman Decl. ¶ 30(g)); Young uses the range of AWP minus 14% to 18% (Young ¶ 134). In the physician-administered context, the range is AWP minus 0% to 10%. (Rosenthal 10.) Hartman terms his overall approach the "yardstick method" because he intends to determine what the market reasonably expected the spread to be on average (e.g., AWP is 25% above the average sales price, ASP), and compare this

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<sup>25</sup> Dr. Berndt notes that Hartman proposes using a "multiple regression analysis" to "attempt in a more sophisticated statistical manner to control for factors other than the manufacturer's alleged illegal behavior" in choosing comparator drugs (Berndt ¶ 217), but that "it is unclear to [Berndt] at this time precisely how Dr. Hartman plans to proceed" with this analysis (Berndt ¶ 218).

number to the actual spread (e.g., AWP is 100% above ASP) to calculate aggregate class-wide damages.<sup>26</sup> (Berndt ¶ 212.)

Hartman does not go into much detail on how to apportion individual damages in Phase II, but he proposes using each TPP's actual contract reimbursement rate (e.g., AWP minus 15%) to determine what rate the TPP would have paid in the but-for world, on the assumption that the actual contract rate takes into account the knowledge and market power of each TPP. (Hartman Decl. attach. F ¶¶ 4-5; Hartman Rebuttal ¶¶ 54, 58, fig. 1-C.) In other words, weaker market participants tend to reimburse at AWP minus 14%, and stronger, more knowledgeable participants tend to reimburse at AWP minus 18%. (Hartman Rebuttal ¶ 58 ("While it is true that the Class includes payors characterized along a variety of dimensions which result in a variety of discounts off AWP and therefore a variety of reimbursement rates . . . reimbursement rates have been found to be consistently within 14%-18% off AWP. This finding argues for the same shaped distribution and the same location on the distribution for the

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<sup>26</sup> Hartman identifies a range of expected ASPs of 20% to 23% below AWP generally in his rebuttal declaration. (Hartman Rebuttal 63.) In his original declaration he varies the ranges of expected spreads depending on who moves market share. He identifies the yardsticks - the percentage amounts that TPPs believe ASPs are below AWP - in the PBM context as being 16% to 33% for single source drugs, and 10% to 20% for multiple source drugs, and in the physician-administered context as being 0% for Medicare and 18% to 33% for the private drugs. (Hartman Decl. ¶ 33.)



avored payors, the least favored payors and the average payor, relative to the artificially inflated AWP . . . .") .) He then would measure the difference between each TPP's but-for payment and the payment that TPP made in the actual world to calculate damages.

Hartman has performed these calculations for several drugs by way of example. Based on his preliminary information, he calculates the "but-for" spread between AWP and ASP in the physician administered context as being in the range of 18% to 33%. (Hartman Decl. ¶ 33.) Under Medicare Part B, he calculates the but-for spread as 0% because it is set by law. Under Hartman's calculation, Vepesid, an injectable, physician-administered drug, demonstrated actual spreads that range from a low of 291% in 2002:Q1 to a high of 24,249% in 2001:Q3. (Hartman Decl. ¶ 37.) Hartman assumes that reimbursement was made on average at AWP minus 15%. (Hartman Decl. ¶ 37, Table 3A.) After calculating a but-for AWP, his calculations result in \$158 million in aggregate overcharges for this NDC for the period from 1997 to 2002. (Hartman Decl. ¶ 37.)

Defendants disagree with Hartman's contention that AWP is the driving force behind reimbursement in the physician-administered context, and claim that individual issues predominate. They argue that insurers individually negotiate physician fee schedules with doctors or doctor groups, which

often have strong leverage depending on the specialty and geographic location of the practice, and that insurers vary dramatically in sophistication and knowledge about the spreads. Further, defendants argue that it is difficult to disaggregate the "bundle" of negotiated services in order to separate drug reimbursement costs from the fees for administration of the drugs. The most common interdependency is between reimbursement for the drug and reimbursement to the physician for the act of administration, with the former representing a net subsidy for the latter. (Gaier ¶ 62.)

Numerous courts have held that the need to examine individual negotiations or individual contracts to determine injury weighs against class certification, for it requires an unwieldy examination of each transaction to decide if there is proximate cause. See Robinson v. Tex. Auto. Dealers Assoc., 387 F.3d 416, 423-25 (5th Cir. 2004) (reversing certification of class of consumers whose sales contracts contained a tax as a line item separate from the cash price because determining whether a particular consumer negotiated based on the cash price or the bottom line required individual evaluation); Klay, 382 F.3d at 1263-1266 (reversing certification of breach of contract claims by doctors claiming defendants programmed computers to automatically underpay in some situations, where determination of whether doctor was underpaid required an individual evaluation of

each contract and each transaction); Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc., 259 F.3d 154, 187-90 (3d Cir. 2001) (affirming denial of certification where determination of whether class member was injured in particular instance would require evaluation of circumstances of trade, including whether a better price than that obtained by the agent was available based on each class member's characteristics and order specifications); Poulos v. Caesars World, Inc., 379 F.3d 654, 664-66 (9th Cir. 2004) (affirming denial of certification on causation grounds where establishing injury would depend on showing that individual class members were fooled by electronic machines resembling poker games into thinking that machines were programmed to follow random odds of winning at poker); Lienhart v. Dryvit Sys., Inc., 255 F.3d 138, 148-49 (4th Cir. 2001) (reversing certification where determination of liability would depend on whether in each case third parties both received and followed installation instructions from defendant).

In defendants' view, these variables - i.e., market power of doctors and sophistication and market power of TPPs - show why "a common course of conduct is not sufficient to establish liability of the defendant to any particular plaintiff." Moore v. PaineWebber, Inc., 306 F.3d 1247, 1251 (2d Cir. 2002) (holding that liability could not be established by proof of a central, coordinated fraudulent scheme where misrepresentations were not



materially uniform because "each plaintiff must prove that he or she personally received a material misrepresentation, and that his or her reliance on this misrepresentation was the proximate cause of his or her loss"); compare id. with Carnegie, 376 F.3d at 662-63 (holding that class consisting of persons allegedly defrauded by failure of banks and tax preparers to reveal that tax preparer was engaged in self-dealing was properly certified because RICO fraud claims could be separated into common liability claims and individual injury claims).

Defendants' expert Stephen Young, who is not an economist but has industry experience as a consultant, attacks Hartman's expert methodology by arguing that (A) most commercial payors did not negotiate with physicians based on their drug acquisition costs, and even if they did they did not premise those negotiations on the view that AWP was a "signal" of acquisition costs; (B) the reimbursement attributable to a particular physician-administered drug, and the rationale for that reimbursement, cannot be assessed without a consideration of the entire fee schedule of negotiated services; (C) because of the use of the "J-Codes", the analysis of physician-administered drugs will require significant individual inquiry in a manual process to determine the reimbursement level; and (D) unlike in retail pharmacy reimbursement, AWP is not consistently referenced in contracts for the reimbursement of physician-administered

drugs. (Young Sur-Reply ¶ 4.) Young also states that the use of J-Codes in the generic context is particularly nettlesome because one J-Code covers all NDCs from multiple manufacturers.<sup>27</sup> (*Id.* ¶ 44.)

While not critiquing the use of a yardstick in the physician-administered context, the independent expert, Berndt, expresses concern with Hartman's analysis because of the poor quality of the data available. He cites "accounting ambiguities" concerning whether physician-administered drugs were covered as medical or drug benefits and a J-Code classification system that "obfuscated true transaction[] prices and utilization" in concluding that "the quality of general information concerning actual prices for physician-administered services is likely to have been very poor." (Berndt ¶ 228.) He also points out that the "high touch, high cost" characteristics of physician-administered drugs imply that the statistical variance from any

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<sup>27</sup> Plaintiffs hotly contend that Young has submitted material that is misleading, unreliable and so false as to be sanctionable. In particular, they contend that Young misrepresented that contracts were not based on AWP, and that forty-nine percent of the contracts he relied on did not even include a fee schedule. Further, they disagree that it will be too difficult to cross-walk between the "J-Codes" used in physician-administered transactions and NDCs. This shrill debate between Hartman and defendants' experts, Young and White, about the reliability of the underlying data and problems of sample bias is the kind of technical dispute that should not be resolved in a motion for class certification. Rather, it should be the subject of a Daubert hearing. See Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993).

sample of information could be "very high." (Berndt ¶ 229.) To exacerbate the difficulties in deciphering the data, the literature in the public domain is not helpful in the area of generic drugs administered by physicians. (Berndt ¶ 229.) In a follow-up memorandum, Dr. Berndt states that he expects that the cross-walking between the five-digit J-Code and the eleven-digit NDC code that will be necessary to track actual physician-administered drug utilization and unit prices "is more likely to be feasible and reliable for the more recently introduced and typically more expensive biotech physician-administered drugs, and much less likely to be feasible and reliable for older, and in particular, multi-source off-patent and generic products." (Berndt Mem. of Aug. 9, 2005 at 2.) He adds that cross-walking will be less feasible for reimbursements made prior to 2000. (Id.)

The important question in a class certification context is whether after a sneak preview of the issues, the expert approach appears fundamentally flawed -- an issue usually vetted more fully at a Daubert hearing based on a more detailed record.<sup>28</sup> The present record suggests concerns about the feasibility of using the yardstick methodology in the physician-administered context. How will plaintiffs find reliable comparator drugs to

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<sup>28</sup> Track One defendants have filed a motion to strike the Declaration of Raymond S. Hartman under Daubert. That motion is **DENIED** without prejudice.

derive the but-for spread? How difficult is it to get reliable survey data on spreads in light of the ambiguities created by J-Codes and the overall lack of pricing transparency? However, it is inappropriate at this stage of the proceedings to determine on the merits whether Young's analysis of the quality of the data or the market is better than Hartman's. Based on the current cold record, I conclude that Hartman's but-for methodology for calculating damages on an aggregate class-wide basis, while preliminary, is not so insubstantial as to preclude class certification.

The next question is how individual and common legal issues affect predominance. Plaintiffs have asserted claims under state consumer protection laws without demonstrating that those statutes cover corporations. The Court explained in the previous section that many such laws do not cover corporations and others have substantially varying standards and burdens. Therefore, predominance is satisfied only for a statewide class under Massachusetts law, Chapter 93A.

Finally, pursuant to Fed. R. Civ. P. 23(b)(3), this Court must determine whether a class is a superior vehicle for resolving plaintiffs' claims. A key factor in making this determination is manageability, which focuses on pragmatic concerns. Defendants argue that Phase II will consume years of jury time because each defendant will have the right to a jury

trial on its affirmative defenses. Further, defendants argue that because of different levels of knowledge, each TPP would have to prove its expectation as to the spread and the damages suffered as a result of the alleged fraud. The First Circuit approves of the use of bifurcation in class trials, especially where the individual issues are not overly complex. See Smilow, 323 F.3d at 41; Tardiff, 365 F.3d at 6-7. Nonetheless, the court must be careful to avoid certifying a class where

[c]ommonality among class members on issues of causation and damages can be achieved only by lifting the description of the claims to a level of generality that tears them from their substantively required moorings to actual causation and discrete injury.

In re Fibreboard Corp., 893 F.2d 706, 712 (5th Cir. 1990).

The Court is concerned that the proposed bifurcated trial may prove to be unmanageable, given that Phase II appears to require a separate individualized proceeding for each TPP. While Hartman's yardstick methodology may demonstrate average injury to the class and aggregate damages, the TPPs' injuries vary based on their individual expectations of the price and their reimbursement rates. While Hartman mentions using actual contract reimbursement rates in Phase II, plaintiffs have not adequately explained how each class member will show where its expectation as to the spread between AWP and ASP falls within the 18% to 33% range (and hence damages) absent an individual



trial.<sup>29</sup> The methodology in Phase II is still abstract. While this is not fatal at this preliminary stage, Klay, 382 F.3d at 1259, plaintiffs will have to provide more details in order to survive a Daubert challenge.

Additionally, plaintiffs admit that defendants may be entitled to a jury trial on defenses such as when, if ever, individual TPPs had sufficient knowledge to trigger the statute of limitations and whether the market power of the doctors with whom a TPP dealt was an intervening cause of damages, breaking the causal chain. To further complicate matters, the allegations span a decade, requiring individualized inquiries concerning each TPP in different time periods. While it is conceivable that a method such as grouping categories of class members (as suggested by the First Circuit in Tardiff) may be feasible -- particularly since the number of TPPs covering physician-administered drugs in Massachusetts would be a small subset of the national class --

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<sup>29</sup> Bifurcation of a trial must be carefully crafted to avoid violating the Seventh Amendment by subjecting jury determinations made at the first phase to reevaluation at the second phase. See Blyden v. Mancusi, 186 F.3d 252, 268, 271 (2d Cir. 1999) (reversing judgments in favor of two plaintiffs because the first jury found that there had been illegal "reprisals" generally by the defendants and the second jury was asked to specify whether particular acts were illegal reprisals against particular plaintiffs); Matter of Rhone-Poulenc Rorer Inc., 51 F.3d 1293, 1303 (7th Cir. 1995) (reversing certification where first jury was to determine whether defendants acted negligently generally in failing to screen blood for HIV and second jury was to determine damages and defenses such as proximate cause and comparative negligence, because findings pertinent to defenses necessarily overlapped with findings pertinent to liability).

plaintiffs have failed to explain why class certification is superior if an extensive separate trial will be needed for each TPP at the damages phase.

However, the need for individualized proceedings on damages does not necessarily defeat class certification because the Court has the authority to certify a class for liability only pursuant to Rule 23(c)(4)(A) and decertify the class for damages. This approach is a logical option if plaintiffs' Phase II methodology does not survive a Daubert motion. Because the Court will have to try the claims that defendants fraudulently inflated AWP's of physician-administered drugs in the Medicare Part B trial, it makes sense to try the common claims involving the physician-administered drugs together in one trial with subclasses for each manufacturer.

Therefore, the motion to certify a class of TPPs and consumers paying for physician-administered drugs is ALLOWED with respect to claims under Chapter 93A involving drugs priced at a discount off of AWP. In the context of generic physician-administered drugs reimbursed through private TPPs, plaintiffs have not provided an adequate description of how the scheme or the but-for yardstick could work with generic pricing based on a commercial MAC. MAC varies from payor to payor, from contract to contract, and in some instances, from transaction to transaction. (Gaier Surreply ¶ 53.) Accordingly, generics will be considered

only to the extent that the price in the contract between the TPP and physician is expressly predicated on AWP.

**VI. CLASSES TWO AND THREE: STATE LAW AND RICO CLAIMS PERTAINING TO SELF-ADMINISTERED DRUGS**

Plaintiffs seek to certify third-party payor and consumer classes in the area of self-administered drugs and specialty pharmacy drugs. The proposed second class includes the state consumer protection law claims; the proposed third class includes the RICO claims and the state common law conspiracy claims. While not disputing that the proposed classes satisfy the Rule 23(a) factors, defendants strenuously argue that the individual issues involving each TPP and consumer class member far outweigh any commonality among the class members' claims.

Plaintiffs' core contention is that each PBM enters into an agreement with each manufacturer to defraud TPPs and consumers. In RICO parlance, this unlawful relationship is the RICO "enterprise." 18 U.S.C. § 1962(c). Under the common law claims, the agreement to defraud constitutes the conspiracy. Plaintiffs allege that manufacturers typically give PBMs secret rebates that are not disclosed to TPPs. Even if they are aware that some rebates exist, TPPs are not cognizant of the size of the rebates.<sup>30</sup> Because PBMs typically gain a large share of revenue

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<sup>30</sup> It is worth noting that the Congressional Budget Office recently conducted a study on whether PBMs and manufacturers

from rebates from manufacturers, sometimes more than they do from administrative fees from insurers (Schondelmeyer ¶ 76), their financial interest lies in their relationship with drug manufacturers. This accounts for plaintiffs' allegation that there is a conspiracy between the drug manufacturers and the PBMs at the expense of their TPP clients.

Circuits have formulated different standards for evaluating predominance for proposed classes under RICO. See Poulos, 379 F.3d at 666 n.3 (noting circuit split). The Fifth Circuit has adopted a presumption against certification of RICO cases. See Sandwich Chef of Tex., Inc. v. Reliance Nat'l Indem. Ins. Co., 319 F.3d 205, 219 (5th Cir. 2003). The Seventh Circuit disagrees. See Carnegie, 376 F.3d at 663. Circuits also disagree on the certifiability of nationwide classes involving claims of fraud where reliance must be proved. Compare Sandwich Chef, 319 F.3d at 205 ("Fraud actions that require proof of individual reliance cannot be certified [under Rule 23(b)(3)] . . .

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should be forced to disclose the true acquisition price of drugs, and decided that in the situation of a partial oligarchy, as exists where several patent-protected products are competing for market share, secrecy is beneficial to competition. (Berndt ¶ 164.) This is because manufacturers would not give certain purchasers large discounts if that would mean that all purchasers would demand the same discounts. (Berndt ¶¶ 163-64.) Berndt notes that some economists believe secrecy also helps prevent implicit collusion on price among oligarchical manufacturers (Berndt ¶ 150), and that the FTC "has reinforced the conclusion that mandated increased cost transparency is likely to increase rather than decrease consumers' prices" (Berndt ¶ 163). Plaintiffs disagree with this line of reasoning.

. .") with Prudential Ins., 148 F.3d 283 at 315 ("[T]he presence of individual questions as to the reliance of each investor does not mean that the common questions of law and fact do not predominate.") (citation omitted).

Plaintiffs emphasize that the First Circuit differs from other circuits in that it is not necessary to prove direct reliance on misrepresentations to establish liability. See Systems Mgt., Inc. v. Loisel, 303 F.3d 100, 104 (1st Cir. 2002) ("[C]riminal fraud under the federal statute does not require 'reliance' by anyone: it is enough that the defendant sought to deceive, whether or not he succeeded."); Carnegie, 376 F.3d at 662 (stating that Second, Fourth, and Fifth Circuits require direct reliance); Summit Props Inc. v. Hoechst Celanese Corp., 214 F.3d 556, 560 n.16 (5th Cir. 2000) (noting that Third, Sixth, Seventh, Eighth, and Eleventh Circuits also require direct reliance); cf. Bank of China, N.Y. Branch v. NBM L.L.C., 125 S. Ct. 2956 (2005) (granting petition for writ of certiorari on the question of whether "civil RICO plaintiffs alleging mail and wire fraud as predicate acts must establish 'reasonable reliance'"). In Loiselle, the First Circuit held that underpaid workers could recover damages against their employer, a cleaning company that had filed false invoices with a college being cleaned. 303 F.3d at 101-103. The defendant admitted that but-for its false invoices, the college would have insisted that the defendant



comply with the prevailing wage laws. Id. at 103. The defendant contended, however, that it never made false statements to the workers, nor did the workers rely on defendant's false statements to the college. Id. The First Circuit held that direct reliance on such statements is not required by the RICO statute; however, it stated that it was essential that plaintiffs show proximate cause, for

proximate cause - largely a proxy for foreseeability - is not only a general condition of civil liability at common law but is almost essential to shape and delimit a rational remedy: otherwise the chain of causation could be endless.

Id. at 104. Compare id. with Sandwich Chef, 319 F.3d at 222-23 (holding that "a RICO predicate act 'visited upon a third person' is generally too remote to permit a recovery from a person who complains of injury flowing from that act," with narrow exception for "direct and contemporaneous result[s]"). "Reliance is doubtless the most obvious way in which fraud can cause harm, but it is not the only way." Loiselle, 303 F.3d at 104.

Applied to this case, Loiselle establishes that the plaintiff class members need not have heard or directly relied on the AWP's sent by defendants to the publishers (which are the fraudulent acts alleged by the SAMCC). However, class members must still demonstrate a link between defendants' sending the AWP's to publishers and the injury class members suffered.

Young argues that Hartman's analysis of the methodology for calculating class injury and aggregate damages is fundamentally flawed in the PBM context because of the significant variation in contractual terms in PBM-TPP agreements, particularly with respect to rebates. (Young Decl. ¶¶ 211-12.) According to Young, payors either (a) do not delegate the rebate process to the PBM; (b) delegate a portion of that authority and retain the right to obtain rebates directly from the manufacturer; or (c) delegate the authority to the PBM and negotiate what portion will be retained by the PBM as an administrative fee and what portion the TPP will receive. (Young Decl. ¶ 213.) For payors that do elect to delegate all or part of the process of negotiating with manufacturers for rebates, the level of rebate pass-through varies widely, from 0% to 100%. (Young Decl. ¶ 214.) Some TPPs also elect to obtain a guaranteed rebate per script. (Young Decl. ¶ 214.) One study demonstrated that on average, 79% of rebates were passed through to the TPP. (Young Decl. ¶ 214.)

Plaintiffs raise two arguments to demonstrate that certification is appropriate despite these differences among class members. First, they argue that defendants' conduct impacted the baseline from which negotiations were made, thereby injuring all members of the class. The cases plaintiffs cite employing this "baseline-impact" reasoning are primarily antitrust cases, a key distinction because it may be assumed in

those cases that by preventing competition in a typical market defendants have raised prices to all purchasers. See, e.g., Linerboard, 305 F.3d at 151-52 ("If, in this case, a nationwide conspiracy is proven, the result of which was to increase prices to a class of plaintiffs beyond the prices which would obtain in a competitive regime, an individual plaintiff could prove fact of damage simply by proving that the free market prices would be lower than the prices paid and that he made some purchases at the higher price."); Klay, 382 F.3d at 1256; Lorazepam, 202 F.R.D. at 29-30 ("[W]hen a defendant is alleged to have participated in a nationwide price-fixing conspiracy, impact will presumed as a matter of law, and the predominance requirement of Fed.R.Civ.P. 23(b)(3) will be satisfied."); In re Cardizem CD Antitrust Litig., 200 F.R.D. 326, 344-46 (E.D. Mich. 2001); Terazosin, 220 F.R.D. at 696-97; In re Auction Houses Antitrust Litig., 193 F.R.D. 162, 166 (S.D.N.Y. 2000) ("Price fixing conspiracies, at least to the extent they succeed in fixing prices, almost invariably injure everyone who purchases the relevant goods or services.").

Here, plaintiffs do not allege an antitrust conspiracy to fix prices, but rather allege a conspiracy between each PBM and each manufacturer, which allegedly defrauded TPPs by providing PBMs with secret rebates and by inflating AWP to obtain favorable formulary placement. (Hartman Decl. attach. E ¶ 12.)

Defendants argue that the PBM, wholesale, and pharmacy markets for the procurement of prescription drugs are highly-competitive; therefore, unlike in a price fixing conspiracy, "payors can leverage this competition to dissipate the effects of the alleged AWP scheme." (Gaier ¶ 31.) Payors could simply switch to a competitor PBM if they were not receiving competitive prices. (Gaier ¶ 32.) Supporting this theory, the FTC has repeatedly stated that competition among PBMs is vigorous (a point with which Professor Berndt agrees).<sup>31</sup> (Berndt ¶¶ 206, 209.) This means that knowledge of the availability of rebates would be widespread because of the marketing by PBMs. Hartman disagrees that PBMs are competitive with each other. (Hartman Rebuttal ¶ 65.) He points to (disputed) evidence that some PBMs have substituted higher cost drugs in the mail-order context and that post-contractual self-dealing is prevalent among PBMs (Hartman Decl. attach. C ¶¶ 23-26) to support his theory that PBMs substitute higher cost drugs on their formularies to obtain higher rebates or greater AWP-based administrative fees (Hartman Decl. attach. E ¶ 12). This debate cannot be resolved on this record. Even assuming a conspiracy between PBM and manufacturers, the anti-trust "base-line impact" paradigm, while analogous, does not neatly match the allegations here because the

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<sup>31</sup> Mr. Navarro, one of defendants' experts, states that PBMs were competitive throughout much of the class period. (Navarro 9.)

key allegation in the SAMCC is that pharmaceutical companies compete (not conspire) with one another for market share by boosting the AWP of competitive drugs or offering rebates. The Court would have to look at each arrangement between the PBM and the manufacturer with respect to each TPP for each AWPID to determine whether there was a fraudulent relationship that had a baseline impact on the drug reimbursement rates paid by the TPP.

Second, Plaintiffs rely on the Hartman yardstick methodology as a method of calculating aggregate class damages. They assert they can prove through the economic theory of revealed preferences, through the comparison method, and through surveys that TPPs expected the spread between AWP and AAC or ASP to be no more than 33% for brand-name drugs. Plaintiffs assert that with these methods they can prove that the fraud was the proximate cause of injury (inflated price) even for those with bargaining power and sophistication. (Hartman Rebuttal ¶¶ 50-53, 55, 58.) Using the yardstick, plaintiffs assert they can calculate aggregate class damages or damages per drug.

Here, however, the yardstick methodology has a flaw because, among other things, Hartman does not explain how it takes into account pass-through rebates paid to the TPPs. In the physician-administered context, any rebates were kept by the doctor. In the self-administered context, rebates often flow back to the TPP through the PBMs. Many TPP class members pay AWP minus 14% to



18% for a particular drug minus the negotiated pass through of the manufacturer's rebate plus fees. (Bell 55-56.) In Hartman's original declaration, he stated that "[r]eview of PBM contracts in discovery materials produced to date suggests that such rebates may not be shared with TPPs." (Hartman Decl. ¶ 30(d).) In his reply affidavit, Hartman addresses this issue as to the pass-throughs by asserting that "manufacturer data and/or payor data can be used to calculate rebates actually paid to TPPs" in the Phase II damages trials:

[T]he analysis of overcharges in reimbursement rates can be extended to explicitly account for rebates. Actual manufacturer data and/or payor data can be used to calculate rebates actually paid to third-party payors per unit of drug reimbursed. Absent the AWP scheme, it is presumed that such unit rebates would be reduced . . . . At the Damages Phase of this litigation, I will calculate the extent to which rebates were paid and the extent to which those rebate payments changed in the but-for world, to the extent allowed by the data and by the availability of appropriate yardsticks. However, it should be noted that if I ignore the change in rebates, the calculation of overcharges based upon reimbursement rates . . . and actual rebates alone will be conservative to Defendants.

(Hartman Rebuttal Decl. ¶ 60.) This preliminary and tentative solution is unsatisfactory because the aggregate damages per drug calculated in Phase I are likely to be too high unless the pass-through rebates are taken into account when measuring the reimbursement rates paid by TPPs. (Gaier ¶¶ 55-56.) Additionally, Hartman's bald explanation for how he would address

rebates contradicts in part his stated position that "[n]or are [manufacturers] fully informed of the extent to which the PBMs share rebates with their client TPPs." (Hartman Decl. attach. C ¶ 25(a).) In addition, even where there are no pass-through rebates, the audit rights possessed by some TPPs would affect the expected spreads.

Applying the predominance requirement to the common and individual issues discussed, the Court finds that common issues do not predominate. While establishing the background of the alleged fraud and the defendants' conduct will involve substantial common issues, there are significant issues which are not common. The contractual relationship between each TPP and each PBM may commonly reference AWP as the benchmark, but there the similarity ends because the contracts provide different bundles of services and rebates. There are also different levels of sophistication and knowledge among the TPPs. Because of the variability in TPPs' contracts with PBMs, plaintiffs are unable to show that each TPP class member paid more than it would have in the absence of the fraud via common proof. Significantly, many putative TPP class members (including those covering roughly 25% of persons with private insurance) purchased drugs themselves and therefore had first hand knowledge of the acquisition costs for drugs. (Young Decl. ¶¶ 5, 153.)

Finally, even if Hartman's methodology could be fine-tuned,

the class of all 11,000 TPPs is not manageable. It is true that many cases state that the need for an individualized damage proceeding need not always preclude class certification. However, most of those cases involve damages calculable according to a formula or template. See Smilow, 323 F.3d at 40 ("Common issues predominate where individual factual determinations can be accomplished using computer records, clerical assistance, and objective criteria - thus rendering unnecessary an evidentiary hearing on each claim."); Klay, 382 F.3d at 1260 ("Of course, there are also extreme cases in which computation of each individual's damages will be so complex, fact-specific, and difficult that the burden on the court system would be simply intolerable . . . .").

As in the physician-administered context, damage determinations would necessitate individual jury trials in which defendants can assert defenses and challenge the TPP's actual expectations of the range. The issues are more complicated in this context given the complex web of participants, and the higher level of understanding of this market in general. This would not be the simple administrative proceeding before a master suggested by plaintiffs.

Holding 11,000 individual damages trials in Part II is a management nightmare, and class certification is not a superior method for resolving the fraud claims of each TPP. Many TPPs

(unlike the sick elderly in the first class) are well-heeled corporations (Aetna, Cigna, Blue Cross/Blue Shield companies) able to defend their interests if they believe they have been defrauded. Plaintiffs assert that thousands of Taft-Hartley funds do not have the resources to devote to the preparation of the case on an individualized basis, but I have no "sorting hat" to cluster the plans.

Essentially, I am persuaded that the individual issues of each TPP will overwhelm the common questions and render the class action inefficient. The argument that this would be a manageable class is too large a pill to swallow. See In re Sch. Asbestos Litig., 789 F.2d 996, 1011 (3d Cir. 1986) (stating that "manageability is a serious concern" where class pressed claims against fifty defendants for "[i]n a sense, a whole industry is on trial," but allowing case to proceed with the caveat that certification was conditional); Robinson, 387 F.3d at 426 (reversing certification where district court "adopted a figure-it-out-as-we-go-along approach" to dealing with the fact that several hundred defendants would each offer an individualized defense).

I inject one last point: I have inadequate information about specialty pharmacies to certify a class involving reimbursements by TPPs for drugs sold by them.

Accordingly, I **DENY** the motion to certify classes two and

three.

#### VII. ORDER

For the reasons stated above, I order the following:

(1) The motion to certify a nationwide class of Medicare Part B beneficiaries is deferred pending plaintiffs' proposed amendment to add individual class representatives. I will then certify the nationwide class (except in those states where class actions are not authorized or notice was not given) if adequate individual class representatives are found.

(2) The motion to certify a nationwide class of TPPs that pay MediGap supplemental insurance to cover Medicare co-payments is DENIED, but the Court will certify a statewide class under Mass. Gen. Laws ch. 93A.

(3) The motion to certify a nationwide class of TPPs and consumers paying for physician-administered drugs in the private context based on AWP is DENIED, but the Court will certify a statewide class for brand-name drugs and those generic drugs for which reimbursement was explicitly based on AWP, not MAC pricing.

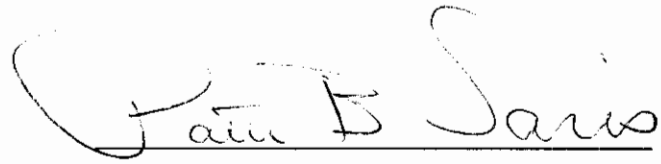
(4) The motion to certify a nationwide class of consumers and TPPs paying for self-administered drugs is DENIED.

(5) Plaintiffs shall file their proposed amendment adding individual class members within sixty days of the date of this opinion, together with supporting documentation. Any depositions



shall take place within thirty days of the amendment. Any challenge to adequacy or typicality shall be filed within forty-five days of the amendment. Any opposition shall be filed fourteen days later. There will be no replies, sur-replies, supplemental replies, letter briefs, motions to strike, or similar subterfuges for more briefing opportunity. The parties are limited to twenty pages per side. There shall be no individual briefs by each defendant. The parties shall be reasonable with respect to any appendices. The same brief and page limitations apply to any motion for reconsideration.

(6) Plaintiffs shall propose a class certification order consistent with this decision within sixty days of the date of this opinion. The Court intends to issue one order certifying the class.

A handwritten signature in cursive script, reading "Patti B Saris", written over a horizontal line.

PATTI B. SARIS

United States District Judge